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Impact of US Public Health Service increased risk deceased donor designation on organ utilization

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Abstract

Under US Public Health Service guidelines, organ donors with risk factors for human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) are categorized as increased risk donors (IRD). Previous studies have suggested that IRD organs are utilized at lower rates than organs from standard risk donors (SRD), but these studies were conducted prior to universal donor nucleic acid test screening. We conducted risk-adjusted analyses to determine the effect of IRD designation on organ utilization using 2010–2017 data (21 626 heart, 101 160 kidney, 52 714 liver, and 16 219 lung recipients in the United States) from the Organ Procurement and Transplantation Network. There was no significant difference ($P < .05$) between risk-adjusted utilization rates for IRD vs SRD organs for adult hearts and livers and pediatric kidneys, livers, and lungs. Significantly lower utilization was found among IRD adult kidneys, lungs, and pediatric hearts. Analysis of the proportion of transplanted organs recovered from IRD by facility suggests that a subset of facilities contribute to the underutilization of adult IRD kidneys. Along with revised criteria and nomenclature to identify donors with HIV, HBV, or HCV risk factors, educational efforts to standardize informed consent discussions might improve organ utilization.

Keywords

clinical decision-making; clinical research/practice; donors and donation: deceased; guidelines; infectious disease; organ acceptance; organ procurement and allocation; organ transplantation in general

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

DISCLOSURE

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation.*

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the Organ Procurement and Transplant Network (OPTN). Restrictions apply to the availability of these data, which were used under license for this study. Data are available with the permission of OPTN.

1 | INTRODUCTION

Since the emergence of the human immunodeficiency virus (HIV) epidemic, the US Public Health Service (PHS) has made recommendations to reduce the risk of HIV transmission associated with organ transplantation.[1–3] Historically, these recommendations included strategies to identify HIV-related risk factors among donors based in part on characteristics that have been recognized to be associated with transmission to recipients.[3] Recommendations also included laboratory testing of donors initially to detect anti-HIV antibodies, with additional testing added as technologies such as nucleic acid testing (NAT) have been developed.[1] In 2013, based on transplant-related transmission events and reports of poor recipient outcome from hepatitis B (HBV) and C (HCV) transmission, the PHS released a revised guideline to reduce the risk of unintended HIV, HBV, and HCV transmission through transplantation.[1] These recommendations were enhanced by recommending specific recipient informed consent, expanded donor HCV (anti-HCV antibody and NAT) and HBV (surface antigen and core antibody) laboratory screening, and recipient monitoring for evidence of disease transmission. The recommendations were not intended to restrict transplantation but to facilitate appropriate donor laboratory screening, enhance informed decision making by recipients, and ensure prompt recognition of donor-derived disease transmission so treatment could be initiated.

Per the 1994 guideline, organ donors were screened for HIV using serologic testing. Donors with risk factors for HIV infection and transmission to recipients were designated “Centers for Disease Control and Prevention (CDC) High Risk” donors.[3] The 2013 guideline modified terminology to “Increased Risk Donor (IRD)” and recommended HCV NAT for all donors and HIV NAT or p24 antigen testing for IRD.[1] “Increased” was adopted over “high” to convey the continued, though small, possibility of donor-derived disease transmission despite NAT. As a result of the opioid epidemic, the proportion of the donor population that is categorized as IRD has increased.[4] IRD has a higher prevalence of HBV and HCV infection in comparison with standard risk donors (SRD).[4] Several studies have reported underutilization of organs from IRD, but have methodological limitations that reduce the relevance of previous estimates of underutilization for current decision making. The most substantial limitations of previous studies were inadequate control for donor HCV serostatus and the use of limited risk adjustment models[5,6] as well as other limitations such as the exclusion of extended criteria donors (ECD) or organs recovered after cardiac death,[5] and older study time-frames.[5,7] Understanding the impact of IRD designation on organ utilization is important. Studies have shown that patients awaiting transplantation who decline IRD organs have increased mortality compared to patients who accept IRD organs.[6,8] Additionally, effective therapies are available for HIV, HBV, and HCV.

To determine whether IRD categorization is associated with decreased utilization of organs, we analyzed data obtained from the Organ Procurement and Transplantation Network (OPTN).* We developed separate risk adjustment models for adult and pediatric heart, kidney, liver, and lungs and tested for a relationship between IRD categorization and underutilization after accounting for these risk adjustment factors, first with all donors, then

*https://optn.transplant.hrsa.gov/

with HBV and HCV NAT and/or serology-positive donors removed. These donors were removed because, while a large numbers of HBV and HCV NAT or antibody-positive donors are designated IRD, per the 2013 guideline, use of these organs is characterized as potentially resulting in expected donor-derived infection.[1] Decisions to accept or decline these organs are more likely to be due to the test results rather than donor IRD status. In addition to quantifying utilization, we further examined utilization by region and organ type. CDC, Health Resources and Service Administration (HRSA), and other federal partners are currently considering revisions to the 2013 guideline recommendations. Utilization effects described are further discussed in context of future guideline recommendation revisions.

2 | METHODS

Data reported by US organ procurement organizations and transplant centers to the OPTN from January 1, 2010-December 31, 2017 were analyzed. Transplant procedures were identified for adult (age ≥18 years) and pediatric (age <18 years) heart, kidney, liver, and lung recipients and were matched to deceased donor records. The OPTN database included 70 414 deceased donors during 2010–2017, including 4157 deceased donors from whom a heart, kidney, liver, or lung was not recovered (ie, pancreas or intestines were recovered from these donors). Forty deceased donors whose IRD status was unknown were excluded. Transplant and recipient characteristics were obtained for 191 719 total transplants (21 626 hearts, 52 714 livers, 16 219 lungs, and 101 160 kidneys) performed during this period. Simultaneous kidney-pancreas transplants were reclassified as kidney transplants, leading to 2305 additional kidney transplants. Sixty-two heart-lung transplants were excluded because of the small number of recipients of this anatomically intact organ combination. The analyses were stratified by organ. Donors designated “CDC High Risk” or “PHS Increased Risk” were categorized as IRD for these analyses.

2.1 | Utilization rate calculation

Previously described methods were used for estimating organ utilization rate.[5,7] Utilization estimate rates were calculated with individual recipient transplant surgery as the numerator and potential donors as the denominator. For heart utilization, only a single donor can be associated with a single recipient. However, for liver, lungs, and kidneys, a single donor can be associated with multiple recipients. To ensure that lung and liver donors are not counted twice, lungs or livers from a single donor that were transplanted to either 2 adult or 2 pediatric recipients were excluded. Because pediatric and adult recipients were examined separately, lungs and livers from a single donor that were transplanted to 1 adult and 1 pediatric recipient were retained for the analysis. Each deceased donor was assumed to have 2 kidneys that can be recovered for transplant, and each donor is therefore duplicated in the denominator of the utilization rate. En-bloc or sequential kidney transplants were counted as a single organ.

The accuracy of the utilization rate estimation is dependent on correctly matching the denominator to the recipient population. Because adult heart, kidney, liver, and lung recipients were most likely to receive an organ from a donor aged >15 years (Figure S1), the adult utilization rate was calculated based on donors aged >15 years. Pediatric heart, liver,

and lung recipients are most likely to receive an organ from donors aged <21 years, but most pediatric kidney recipients received organs from donors aged 12–35 years. The pediatric utilization rate was calculated using donors aged <21 years and a sensitivity analysis using donors aged 12–35 years was performed.

2.2 | Risk adjustment models

Risk adjustment models to adjust for the association between donor characteristics and organ transplant were developed using logistic regression with stepwise model selection. Transplants that occurred between January 1, 2014 and December 31, 2017 were used to fit the risk adjustment models. Risk adjustment variables (Table S1) were identified from the deceased donor database using variables based on the Scientific Registry of Transplant Recipients posttransplant outcomes models.[9] A risk adjustment model was obtained separately for each organ, stratified by age with entry and stay P values set to .2 and .05, respectively (Table 1, Tables S2–S9). An additional 2-level time-period variable (2010–2013 or 2014–2017) was used to compare utilization before and after the 2013 PHS Guideline publication.[1] This time-period main effect represents changes in overall utilization (IRD and SRD combined), and the interaction between time period and IRD status represents differential changes for IRD compared to SRD organs associated with the PHS Guideline revision made in 2013.[1]

Because kidney donors were duplicated in the denominator when calculating utilization rates, the fit of the risk adjustment model was tested using a generalized estimating equation (GEE) approach to account for donor duplication.[10] All parameters in the risk adjustment model for adult kidneys were found to be statistically significant when the 0047EE model was used.

The risk-adjusted utilization rate for IRD (SRD) organs was calculated by multiplying the observed overall utilization rate (independent of IRD status) by the ratio of the utilization rates predicted from the null model for IRD (SRD) and the risk-adjusted utilization rate for IRD (SRD) donors. The risk-adjusted logistic regression model was used to test for differences between IRD and SRD rates. Finally, the model was used to predict the number of underutilized IRD organs (ie, the number of organs not utilized as result of IRD categorization), calculated as the difference between the predicted number of transplanted organs under the fitted model and the model with the IRD parameter set to zero.[6] Because including donor HBV/HCV test result (antibody and/or NAT) status as part of a logistic regression model might not appropriately control the potentially complex relationship between donor HBV/HCV status, IRD status, and organ utilization, the utilization rate analyses were repeated after excluding donors with positive test results for HBV or HCV (antibody and/or NAT).

2.3 | Center-level model

Additional analyses were conducted to determine whether statistically different proportions of IRD organs transplanted in each facility (also referred to as transplant center) compared with the OPTN regional rate (ie, the expected rate) could drive underutilization estimates nationally. For these analyses, a binomial distribution was assumed for each transplant

center, j, with parameters n_j and p, where n_j is the number of transplants in facility j and p is the proportion of IRD organs transplanted in the OPTN region corresponding to facility j. The binomial cumulative distribution function was used to obtain the probability that any randomly observed IRD organ proportion could be less than or equal to the observed facility proportion, under the null hypothesis that the center does not underutilize IRD organs. Under the null hypothesis (ie, facility utilizes IRD organs at the regional rate), 2.5% of transplant centers would be expected to have a probability ≤.025. If the proportion of centers <0.025 (or ≥0.975) is more than expected under the null hypothesis, this suggests underutilization (or overutilization) of IRD organs.

All analyses were performed using SAS software, version 9.4 (SAS Institute Inc., Cary, NC).

3 | RESULTS

3.1 | IRD and SRD organ utilization rates

Between January 1, 2010 and December 31, 2017, 21 626 heart transplants (18 368 to adult recipients and 3258 to pediatric recipients) were reported to OPTN (Figure 1). There were 52 714 liver transplants (48 770 to adult recipients, 3944 to pediatric recipients), most of which were transplanted as a whole liver to a single recipient. A segmented liver from a single donor was transplanted to 2 adult recipients in 58 cases and to 2 pediatric recipients in 98 cases, which were excluded to avoid double-counting donors. The 513 segmented livers that were transplanted to 1 pediatric recipient and 1 adult recipient were included in the analysis. The majority of the 16 219 lung transplants (15 835 to adult recipients; 384 to pediatric recipients) involved a single donor with a single recipient, although 2490 lungs from 1245 donors were transplanted to 2 different recipients. Of these, lungs from 543 donors to 1086 adult recipients were each transplanted at the same center and were excluded to avoid being counted twice.

There were 101 160 total kidney transplants (97 343 adult recipients; 3817 pediatric recipients), which included 2422 recipients (2363 adult recipients; 59 pediatric recipients) who received both kidneys from a single donor, either en-bloc or sequentially, and were therefore counted as a single event for the numerator and the denominator.

Table 1 shows the risk adjustment models for the outcome event of heart, kidney, liver, or lung transplant, fit separately for adult and pediatric recipients. The full models for each organ (adult and pediatric), including estimates, odds ratios, and P values are presented in Tables S2–S9. Unadjusted utilization rates are significantly lower ($P < .05$) for all IRD organs (adult and pediatric) compared to the utilization rates of the corresponding SRD organs, except IRD adult hearts and livers, which had higher utilization rates compared to SRD adult hearts and livers (Table 2). After initial risk adjustment, and including HBV- and HCV-positive donors in the model, the utilization rates were significantly lower ($P < .05$) for IRD adult kidneys, hearts, and lungs and IRD pediatric kidneys and hearts transplanted during both time periods and for IRD pediatric livers and lungs transplanted during 2010–2013, compared to the utilization rates of the corresponding SRD organ. There was no significant difference ($P < .05$) between the risk-adjusted utilization rates of adult livers

transplanted during both time periods and pediatric livers and lungs transplanted during 2014–2017 from IRD and SRD donors. The estimated number of underutilized organs per year was higher for 2014–2017 compared to 2010–2013, except for adult hearts and pediatric livers and lungs. The results for pediatric kidneys did not change when the inclusion criteria for donors was changed from <21 years to 21–35 years.

The proportion of SRD and IRD donors that were HBV or HCV positive was 6.2% and 23.5%, respectively. After excluding donors with positive test results for HBV or HCV, the risk-adjusted utilization rates were significantly lower ($P < .05$) for IRD adult kidneys and lungs and IRD pediatric kidneys and hearts, compared to the utilization rates of the corresponding SRD organ (Table 3). There was no significant difference ($P < .05$) between the risk-adjusted utilization rates of adult hearts and livers and pediatric kidneys, livers, and lungs transplanted. The estimated annual underutilization of organs due to IRD designation was 148 adult kidneys, 34 adult lungs, and 12 pediatric hearts.

The 8 risk-adjusted statistical models were also run for 2010–2017 excluding HBV- and HCV-positive donors and with the addition of a time-period variable (2010–2013 or 2014–2017) and the interaction between time period and IRD status. The interaction between time period and IRD status was significant for adult heart ($P < .001$), liver ($P < .001$), and lung ($P < .001$), with each showing an incremental increase in utilization rate from IRD donors compared to the utilization rate from SRD donors from 2010–2013 to 2014–2017.

3.2 | Transplant center level use of IRD organs

The proportion of transplants that involved an IRD organ varied by region (Figure 2). Additionally, the proportion of IRD organs transplanted among all transplants varied widely, by center, within each region. Table 4 shows the number of facilities that were below the .025 and above the .975 cumulative probability of their binomial distribution. The number of adult facilities below the .025 cumulative binomial distribution probability was higher than expected (2.5%) for hearts, kidneys, and livers (Table 4). For kidneys, 19.7% of adult facilities had a probability of <.025, suggesting these facilities underutilized IRD kidneys. Hearts and livers also show underutilizing centers, although fewer centers transplant hearts (N = 106) and livers (N = 118) compared to those that transplant kidneys (N = 208). The number of lung transplant centers below the 0.025 threshold was consistent with the expected proportion.

4 | DISCUSSION

Previous studies concluded that there was evidence for underutilization of hearts, kidneys, livers, and lungs in both adult and pediatric patients.[5–7] Our updated analyses demonstrate that with statistical adjustment for variables that may affect organ utilization, and with the exclusion of HBV- and HCV-positive donors, there is no significant difference between utilization of most organs recovered from IRD or SRD donors with the exception of 3 organ types. Furthermore, IRD utilization of most organ types increased compared to SRD utilization in the 4-year period after the 2013 changes to the PHS guidelines, suggesting that changes to the guidelines may have resulted in increased utilization of IRD organs. Between 2014 and 2017, there was underutilization of adult kidneys and lungs and pediatric hearts

recovered from IRD compared with SRD. The underutilization of adult kidneys from IRD donors appears to be attributable to low use by a subset of centers, rather than a broader underutilization across all transplant programs in the United States (Table 5). The underutilization of lungs from IRD donors appears to be more uniformly distributed across programs. We estimate that fewer than 200 kidneys or lungs are underutilized annually due to donor increased risk status, below previous estimates.[5] While efforts to improve the use of IRD kidneys and lungs may modestly increase the number of these transplants in the United States, additional interventions are necessary in order to bridge the gap between the numbers of organs needed and available for patients awaiting transplantation.†

These analyses highlight the importance of risk adjustment when estimating utilization rates from IRD and SRD organs. A previous analysis examining IRD kidney use adjusted for 12 variables.[7] A different study analyzing underutilization of hearts, kidneys, livers, and lungs used a 4-variable risk adjustment model and excluded donation after cardiac death (DCD) donors and ECD[5] and estimated more underutilization than the present study, likely due to the more comprehensive risk adjustment performed in the present study. Several factors might be associated with a recipient or program declining an IRD organ. The “increased risk donor” terminology might result in patient apprehension regarding organ quality or the risk of disease transmission.[5,7,11] Poorer outcomes, including recipient death or graft failure, have previously been attributed to HIV or HCV transmission through transplantation.[12,13] However, effective therapies for HIV, HBV, and HCV are now available with improved outcomes in the setting of transplantation.[14] While we did not evaluate wait times or match efficiency as part of the present study, the lower utilization of IRD lungs observed in the present study might be a result of the higher availability of lungs relative to the number of candidates awaiting transplant, compared to other organs.[1] Because patients waiting for kidney transplants have effective bridge therapies such as hemodialysis and peritoneal dialysis, they might be more inclined to decline an IRD organ compared to patients waiting for liver or lung transplants.

While previous studies have suggested underutilization of hearts from IRD donors,[5–7] we did not observe a statistically significant effect after controlling for HBV- or HCV-positive donor test results. A large proportion of donors with NAT or serologic evidence of HBV or HCV are further designated as IRD (23.5% IRD; 6.2% SRD) as a result of risk behaviors that predispose them to other infections, such as HIV, leading to a potential bias in results when these donors are included. The present findings suggest that patients and providers might decline IRD organs because the donor has a positive test result for HBV or HCV, rather than due to IRD classification.

We observed lower utilization of IRD kidneys in a subset of facilities in the United States, suggesting that underutilization of IRD kidneys might be the result of individual transplant center practices, rather than broader underutilization. These findings underscore the need for improved targeted educational efforts to assist patients and providers when choosing to accept or decline IRD organs. Although HIV, HBV, and HCV transmissions through organ transplantation have been described, with HBV and HCV transmissions reported since the

†https://optn.transplant.hrsa.gov/data/view-data-reports/

implementation of the 2013 guideline, the risk of transmission is low. Enhanced educational materials and interventions targeted for other aspects of transplantation to improve organ utilization have been described.[15–17] Development of standardized educational materials that present available evidence regarding transmission risk and outcomes may enhance IRD-related informed consent discussions between clinicians and patients and increase organ utilization.‡

These findings are subject to the following limitations. The eligible donor population used for these analyses only included individuals from whom at least 1 organ was recovered. Individuals considered for organ donation but from whom an organ was not recovered were not included. The impact on the utilization effects presented here cannot be quantified. The risk adjustment model was based on variables available in the OPTN database. However, additional factors that are not entered in the OPTN database might also impact utilization. The modeling approach included only main effects, and it is possible that some of the included variables (such as DCD and ECD, which have been excluded in previous analyses[5]) require a more complex parameterization in the statistical model (eg, interactions). However, in sensitivity analyses, excluding DCD donors and ECD did not change the results.

Although the present findings suggest underutilization of IRD organs, the magnitude of underutilization is less than previously described.[5,7] Given the morbidity and mortality among patients awaiting transplantation, any efforts to improve organ utilization is a public health priority. CDC, HRSA, and other federal partners are considering revisions to the 2013 PHS guideline recommendations to improve organ acceptance and to reflect advances in transplant-related safety interventions such as NAT, with results available pretransplant. In 2019, the Advisory Committee on Blood and Tissue Safety and Availability will consider the findings of the present study when considering changes to current guideline recommendations. Considerations include reassessment of the term “increased risk,” which might be currently contributing to underutilization.[5] Revisions to the recommendations will be accompanied by efforts to develop standardized educational material to improve the informed consent process, in order to improve utilization. While these efforts are warranted, interventions to prevent and treat end-organ disease are necessary. Additionally, efforts to increase organ donation are necessary to reduce morbidity and mortality among patients with end-stage organ disease.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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‡https://optn.transplant.hrsa.gov/governance/publiC’Comment/clarify’in-formed’Consent’policieS’for’transmittable’disease’risk/

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Abbreviations:

CDC	Centers for Disease Control and Prevention
DCD	donation after cardiac death
ECD	extended criteria donors
GEE	generalized estimating equation
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HRSA	Health Resources and Service Administration
IRD	increased risk donors
NAT	nucleic acid testing
OPTN	Organ Procurement and Transplantation Network
PHS	Public Health Service
SRD	standard risk donors

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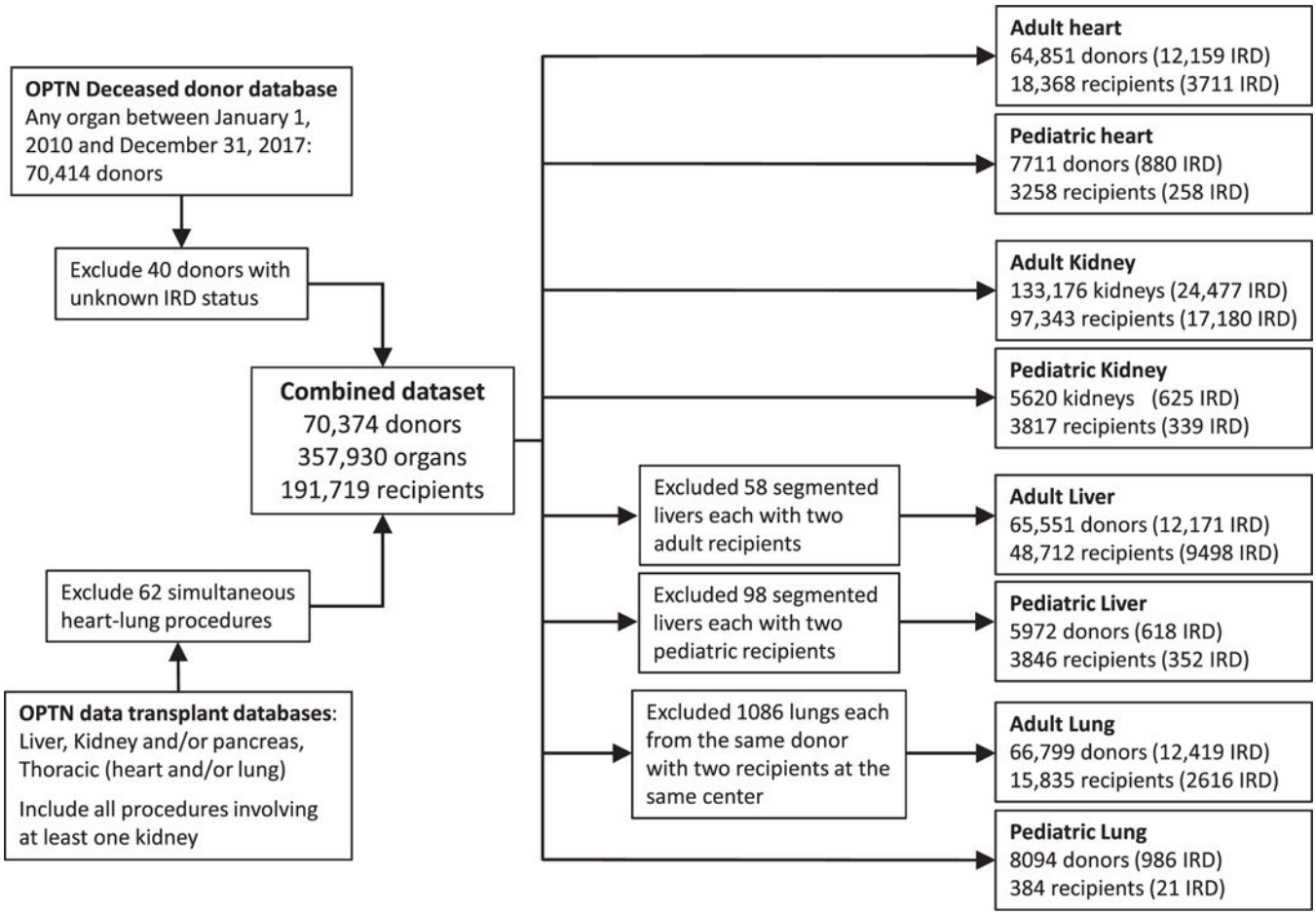

FIGURE 1.

Diagram showing data used in the utilization analyses. IRD, increased risk donors; OPTN, Organ Procurement and Transplantation Network

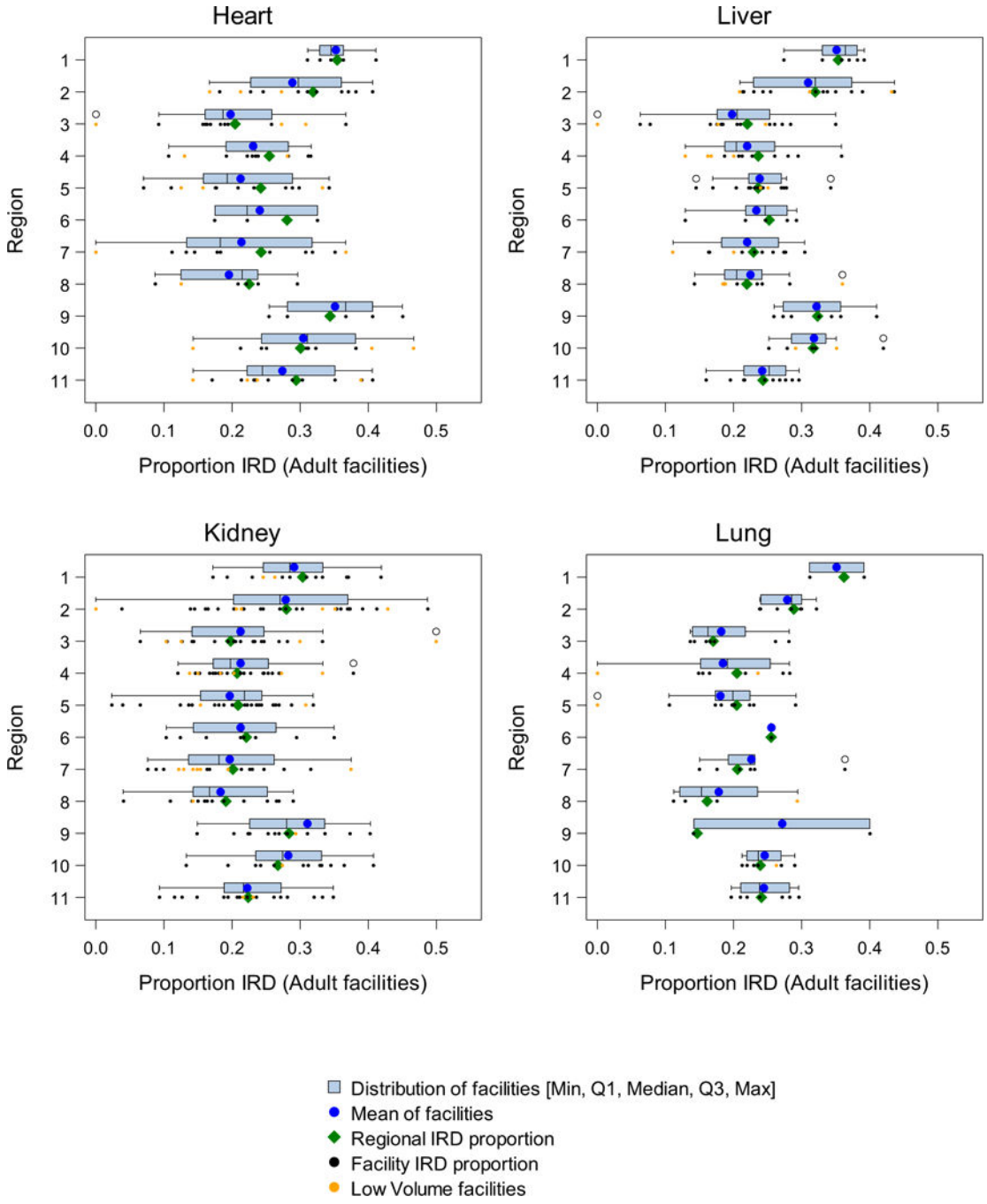

FIGURE 2.

Boxplots of facility–level proportion of transplants that involved an increased risk donor (IRD) organ by Organ Procurement and Transplantation (OPTN) region and organ. For each bar, the box extends between the 25th (Q1) and 75th (Q3) percentiles and the line in the middle of the box represents the median; the horizontal lines extend to the minimum (Min) and maximum (Max), excluding outliers that are plotted as unfilled circles. Low–volume facilities are defined as those with <10 transplants for hearts and lungs and <20 transplants for kidneys and livers. The boxplots are stratified by the 11 OPTN transplant regions:

Region 1 (CT, ME, MA, NH, RI, eastern VT), Region 2 (DE, DC, MD, NJ, PA, WV, northern VA), Region 3 (AL, AR, FL, GA, LA, MS, PR), Region 4 (OK, TX), Region 5 (AZ, CA, NV, NM, UT), Region 6 (AK, HI, ID, MT, OR, WA), Region 7 (IL, MN, ND, SD, WI), Region 8 (CO, IA, KS, MO, NE, WY), Region 9 (NY, western VT), Region 10 (IN, MI, OH), and Region 11 (KY, NC, SC, TN, southern VA)

TABLE 1

List of risk adjustment variables chosen through stepwise model selection for occurrence of transplant to adult and pediatric recipients of heart, kidney, liver, and lung transplants

Model	Risk adjustment variables
Adult heart (29 variables chosen)	Kidney Donor Profile Index; Donor race; Prerecovery thyroxine-T4; Donor cause of death; Donor HBV or HCV positive; Donor given insulin 24 h prior to death; Donor hematocrit; Donor age; Prerecovery steroids; Circumstance of donor death; Terminal lab aspartate aminotransferase; Donor pulmonary infection; Donor Blood pH; Donor blood urea nitrogen; Extended criteria donor (ECD); Vasodilators pre-crossclamp; Donor blood type O; Donor history of cigarette use; Donor clinical infection (blood source); Donor given arginine vasopressin 24 h prior to death; Donor given desmopressin (DDAVP) 24 h prior to death; Donor creatinine level; Number of transfusions given to donor prior to death; Donor total serum bilirubin level; Donor gender; Donor history of diabetes; Donor body mass index (BMI); Donor partial pressure of carbon dioxide; Prerecovery heparin
Adult kidney (21 variables chosen)	Kidney Donor Profile Index; Donor creatinine level; Donor HBV or HCV positive; Extended criteria donor (ECD); Donor given arginine vasopressin 24 h prior to death; Donor history of intravenous drug use; Donor weight (quartiles); Donor blood urea nitrogen; Donor pulmonary infection; Donor race; Donor history of hypertension; Number of transfusions given to donor prior to death; Circumstance of donor death; Donor given desmopressin (DDAVP) 24 h prior to death; Donor history of cigarette use; Donor history of cancer; Prerecovery thyroxine-T4; Donor partial pressure of carbon dioxide; Donor Blood pH; Donor history of other drug use; Donor age
Adult liver (28 variables chosen)	Donation after cardiac death; Donor age; Donor total serum bilirubin level; Terminal lab aspartate aminotransferase; Donor body mass index (BMI); Donor race; Kidney Donor Profile Index; Donor Blood pH; Circumstance of donor death; Donor pulmonary infection; Donor weight (quartiles); Vasodilators pre crossclamp; Terminal lab alanine transaminase; Donor cause of death; Donor history of diabetes; Donor HBV or HCV positive; Donor blood urea nitrogen; Prerecovery heparin; Donor history of intravenous drug use; Donor given desmopressin (DDAVP) 24 h prior to death; Donor hematocrit; Donor height (quartiles); Donor given insulin 24 h prior to death; Donor blood type O; Donor partial pressure of carbon dioxide; Donor clinical infection (blood source); Prerecovery steroids; Donor given arginine vasopressin 24 h prior to death
Adult lung (28 variables chosen)	Kidney Donor Profile Index; Donation after cardiac death; Donor history of cigarette use; Donor cause of death; Donor weight (quartiles); Donor HBV or HCV positive; Circumstance of donor death; Donor Blood pH; Donor age; Terminal lab aspartate aminotransferase; Vasodilators pre-crossclamp; Donor race; Donor clinical infection (blood source); Extended criteria donor (ECD); Donor pulmonary infection; Donor blood urea nitrogen; Donor hematocrit; Donor body mass index (BMI); Donor blood type O; Donor gender; Donor total serum bilirubin level; Prerecovery thyroxine-T4; Prerecovery steroids; Donor history of other drug use; Donor history of cancer; Donor history of intravenous drug use; Number of transfusions given to donor prior to death; Donor given insulin 24 h prior to death
Pediatric heart (17 variables chosen)	Donor age; Donor given arginine vasopressin 24 h prior to death; Donor given desmopressin (DDAVP) 24 h prior to death; Donor given desmopressin (DDAVP) 24 h prior to death; Donor partial pressure of carbon dioxide; Circumstance of donor death; Donor cause of death; Donor Blood pH; Terminal lab aspartate aminotransferase; Donor race; Donor pulmonary infection; Donor hematocrit; Donor blood type O; Donor total serum bilirubin level; Prerecovery thyroxine-T4; Prerecovery steroids; Number of transfusions given to donor prior to death
Pediatric kidney (11 variables chosen)	Kidney Donor Profile Index; Donor creatinine level; Donor height (quartiles); Donation after cardiac death; Circumstance of donor death; Donor total serum bilirubin level; Donor given desmopressin (DDAVP) 24 h prior to death; Donor pulmonary infection; Donor blood type O; Number of transfusions given to donor prior to death; Donor given arginine vasopressin 24 h prior to death
Pediatric liver (18 variables chosen)	Donation after cardiac death; Terminal lab alanine transaminase; Kidney Donor Profile Index; Donor total serum bilirubin level; Donor creatinine level; Donor height (quartiles); Circumstance of donor death; Donor body mass index (BMI); Donor blood type O; Donor pulmonary infection; Donor Blood pH; Number of transfusions given to donor prior to death; Donor blood urea nitrogen; Prerecovery steroids; Donor race; Prerecovery heparin; Donor history of other drug use; Donor hematocrit
Pediatric lung (7 variables chosen)	Donor height (quartiles); Donor blood type O; Donation after cardiac death; Donor Blood pH; Circumstance of donor death; Donor cause of death; Donor history of other drug use

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TABLE 2

Unadjusted and risk–adjusted utilization rates by organ for adult and pediatric recipients, United States, 2010–2013 and 2014–2017

Recipient age group	Organ	Time period	Risk adjustment	Number of organs	Utilization rate		*P* value[a]	Organs underutilized, per year
					SRD (%)	IRD (%)		
Adult	Heart	2014–2017	None	35 079	28.29	31.62	<.0001	−72.6
		2010–2013	Risk-adjusted	29 772	27.93	23.92	<.0001	44.0
		2014–2017	Risk-adjusted	35 079	29.35	28.49	.0297	24.9
	Kidney	2014–2017	None	72 022	74.00	68.54	<.0001	238.5
		2010–2013	Risk-adjusted	61 154	73.80	72.00	<.0001	52.1
		2014–2017	Risk-adjusted	72 022	73.53	69.93	<.0001	256.9
	Liver	2014–2017	None	35 399	73.18	78.47	<.0001	−115.2
		2010–2013	Risk-adjusted	30 152	74.17	73.74	.4041	5.7
		2014–2017	Risk-adjusted	35 399	74.56	74.24	.3553	10.4
	Lung	2014–2017	None	35 547	23.61	20.80	<.0001	61.6
		2010–2013	Risk-adjusted	30 166	22.12	19.87	<.0001	27.0
		2014–2017	Risk-adjusted	35 547	23.22	21.94	.0009	39.9
Pediatric	Heart	2014–2017	None	3916	46.76	30.43	<.0001	22.0
		2010–2013	Risk-adjusted	3795	40.69	31.09	.0001	7.7
		2014–2017	Risk-adjusted	3916	45.71	35.54	<.0001	13.0
	Kidney	2014–2017	None	2870	69.43	56.67	<.0001	13.4
		2010–2013	Risk-adjusted	2750	68.73	61.36	.0045	3.4
		2014–2017	Risk-adjusted	2870	68.35	62.44	<.0001	6.6
	Liver	2014–2017	None	3103	64.46	58.84	.0309	5.6
		2010–2013	Risk-adjusted	2869	65.68	57.75	.0036	4.4
		2014–2017	Risk-adjusted	3103	63.97	62.10	.3185	1.9
	Lung	2014–2017	None	4117	4.62	2.80	.0325	2.8
		2010–2013	Risk-adjusted	3977	5.46	1.34	.0002	3.2
		2014–2017	Risk-adjusted	4117	4.47	3.45	.2456	1.4

IRD, increased risk donor; SRD, standard risk donor.

[a] *P* value testing difference in utilization rates and number of underutilized organs predicted from statistical model.

TABLE 3

Utilization rates by organ for adult and pediatric recipients excluding donors with positive test results (antibody or NAT) for HBV or HCV, United States, 2014–2017

Recipient age group	Organ	Number of organs	Utilization rate		*P* value[a]	Organs underutilized, per year
			SRD (%)	IRD (%)		
Adult	Heart	31 216	31.84	31.51	.4548	7.6
	Kidney	64 299	76.58	73.17	<.0001	148.3
	Liver	31 531	74.58	74.09	.2199	10.9
	Lung	31 686	25.14	23.83	.0024	33.5
Pediatric	Heart	3848	46.16	36.52	<.0001	11.7
	Kidney	2837	69.60	65.66	.0744	4.2
	Liver	3069	64.31	62.73	.4041	1.6
	Lung	4042	4.51	3.62	.3311	1.2

HBV, hepatitis B virus; HCV, hepatitis C virus; IRD, increased risk donor; NAT, nucleic acid testing; SRD, standard risk donor.

[a] *P* value testing difference in utilization rates and number of underutilized organs predicted from fitted risk adjustment model.

TABLE 4

Number of transplant centers for which the upper 2.5% and lower 2.5% cumulative probability that their observed IRD organ transplant rate is the same as their regional rate by organ, United States, 2014–2017

	Adult facilities			Pediatric facilities		
Organ	**n**	**<.025, n (%)**	**>.975, n (%)**	**N**	**<.025 or >.975, n (%)**	**Total N**
Heart	106	7 (6.6)	11 (10.4)	32	1 (3.1)	138
Kidney	208	41 (19.7)	40 (19.2)	37	3 (8.1)	245
Liver	118	12 (10.2)	14 (11.9)	26	1 (3.8)	144
Lung	64	1 (1.6)	5 (7.8)	8	2 (25.0)	72

IRD, increased risk donor.

TABLE 5

Summary of results from analyses

Organ	Adult	Pediatric
Heart	No difference in utilization due to IRD, after excluding HBV/HCV-positive donors	Significant difference in utilization between IRD and SRD organs (11.7 hearts per y)
Kidney	Significant difference in utilization between IRD and SRD organs (148.3 kidneys per y) Underutilization potentially driven by a subset of facilities (41/208)	No difference in utilization due to IRD, after excluding HBV/ HCV-positive donors
Liver	No difference in utilization due to IRD	No difference in utilization due to IRD
Lung	Significant difference in utilization between IRD and SRD organs (33.5 lungs per y). More generalized underutilization nationally	No difference in utilization due to IRD, after excluding HBV/HCV-positive donors
	No difference in utilization	
	Difference in utilization between IRD and SRD appears to be due to subset of transplant centers.	
	Difference in utilization between IRD and SRD appears to be generalized.	

HBV, hepatitis B virus; HCD, hepatitis C virus; IRD, increased risk donors; SRD, standard risk donors.